

### **REMARKS**

Applicant acknowledges with appreciation the interview courteously granted by Examiner Sharimila S. Gollamudi and Primary Examiner Michael G. Hartley to Applicant's undersigned attorney and Applicant (Dr. Keith Johnson), who participated for a portion of the interview by telephone. In the interview, the parties discussed each of the rejections and objection of record, as set forth in the Office Action dated August 18, 2004 as to all of the pending claims, namely (Claims 1-3, 6-11 and 15-16). It is Applicant's understanding with the further explanations provided and several identified clarifying amendments to the claims (which are offered herein), the application would be in condition for allowance. The following remarks seek to briefly summarize the explanations made by the undersigned attorney and Applicant, both in their presentations and in response to questions posed by the Examiners.

### **35 U.S.C.102 Rejections**

Applicant respectfully traversed the rejection of Claims 11-19, 21 and 26 under 35 U.S.C. 102 as being anticipated by Johnson et al (5,997,590). As discussed, the rejection was based upon the references teaching of a diesel fuel/surfactant/water cluster mixture. While Applicant argued (still maintains) that diesel fuel is not "oil" as understood in this art and used in the claimed invention, Applicant agreed to clarify that the term "oil" as used in the claims refers to cosmetic and pharmaceutical oil formulation. The amendment is presented herein, with clear support for it being found in the original specification (e.g., at Page 5) and in the original claims.

It is Applicant's understanding that, with these amendments, the 35 U.S.C. 102 rejections are obviated and would be withdrawn.

### **35 U.S.C.103 Rejections**

Applicant also respectfully traversed the rejection of Claims 1-3,6-11 and 15-26 under 35 U.S.C. 103 (a) as being unpatentable over (i) Johnson et al (5800576), in view of EP 0916621, in further view of Nazzaro-Porro (5385943) and/or (ii) Johnson et al (5800576), in view of Lorenzen (6033678), in further view of Guthauer (5162378). As discussed, Applicant reaffirmed the comments made in response to the prior Offices Actions (incorporated herein by reference) in which the Johnson et al, EP 0916621, and Lorenzen references were cited in various combinations and emphasized the following points:

- The invention as described and claimed herein involves a water-in-oil (w/o emulsion) composition and process applying it the outer layer of skin, in which the water is in a unique water nanocluster structural form (e.g. pentagonal dodecahedral water nanoclusters) of specified dimensions (< 10 nanometers). The composition and process provides previously unknown important functionality (including anti-oxidant benefits for the skin) attributed to the water clusters' unique form and ability to transfer electrons). This important functionality is addressed in greater detail in Applicant's specification at pages 10-11), including the ability (i) to clathrate and deactivate lipid hydrophobes responsible for the stratum corneum barrier and (ii) to chemically scavenge free radicals.

- As to the cited prior art, Applicant acknowledged that the claimed water nanoclusters *per se* are known (as disclosed in Johnson et al). But this water nanoclusters teaching is directed to the use thereof in fuel mixtures/combustion applications, based upon the described ability of the protruding pn orbitals to enhance the combustion process by enhanced transfer of oxygen atoms in the combustion process. In Applicant's prior response, Applicant fully explained the important distinction between the anti-oxidant function of this invention (which is based upon the electrons of the water nanoclusters) and the enhanced oxidation/combustion reaction taught by Johnson et al (which is based upon the oxygen atoms of the water nanoclusters). The Johnson references are directed to combustion applications and do not teach or suggest use of these unique water clusters in applications to the skin or the results obtained.
- As to the cited secondary references (Lorenzen '950) and (EP '621), they do not teach or suggest the use of water nanoclusters formulations of this invention or any analogous water functionality. Lorenzen '950 is directed to the use of its "microclustered water" to form a "template" with a drug or functional component to enhance the delivery thereof; EP '621 is similarly directed, with the approach being to enhance the dispersion of an active ingredient in the "fine water", not to derive benefit from any unique properties of the water *per se*, as in this invention, but simply as a better dispersant in oil-in- water emulsions (not water-in-oil emulsion as claimed herein) in which better dispersion of the material in the water is said

to be achieved. Further, the secondary references characterization of their waters as "microclustered" and "fine", respectively, does not suggest as water structure or criticality thereof, or indeed any quantification thereof, to teach or suggest the specifically defined and unique water clusters of this invention.

- Further there is no rationale or motivation to combine either of these references with the Johnson reference because of the lack of any relationship to Johnson's enhanced combustion/water cluster teachings to the "better dispersion of a functional component" focus of these secondary references. In fact in view of the needs and objectives of these secondary references to provide better dispersion and delivery means if used in dermal delivery applications, would teach away from use of Johnson's "reactive water".
- The cited tertiary references (Nazzaro-Porro '943 which is related to highly specific topical preparation, including an ointment described as a water/oil emulsion, and Guthauer '378 which is related to silicon containing water-in-oil emulsions), add little or nothing. Applicant is certainly are not claiming to be the first to produce water-in-oil emulsions, other than as described and claimed herein.

Applicant summarized his position by stating that the combustion-directed teaching in Johnson of unique water clusters as used herein, together with the use of teaching of the use of vaguely defined "fine or micro" water to enhance the dispersion or means of delivery of other active functional components, is not a teaching or suggestion of this invention. Further, there is

no appropriate basis for this combination of references other than by improper use based upon Applicant's current teachings.

To better recite the invention, amendments are provided herein to all claims both clarify the oil formulations which are used and the minimum water percentage content to avoid any unintended reading of the claims on water nanocluster formulations which may contain small amounts of naturally occurring or incidentally/accidentally produced water nanoclusters. Clear support for these claim amendments are found in the original specification (e.g., at Page 5) and in the original claims. For additional clarification at the Examiner's suggestion, all claims have now been amended to use the term water-in-oil nano-emulsion (instead of water-in-oil emulsion) to more clearly indicate that emulsion contains at least one component (namely the water nanoclusters) that are in the nano-range. Clear support for this clarification is in the original specification.

It is Applicant's understanding that, with these amendments, the 35 U.S.C. 103 rejections are obviated and would be withdrawn.

#### **MPEP 706.03(k) Objection**

Applicant also traversed the MPEP 706.03(k) based objection as to Claim 11 and Claim 26, based upon the Examiner's position alleges that the claims are substantial duplicates. Applicant pointed out that these claims significantly differ in scope disagrees (e.g., <10 nanometers requirement is more expansive than 0.8 to 10 nanometers) and it is Applicant's understanding that with this explanation, the objection would be obviated and withdrawn.

**Timely Response**

Applicant is filing concurrently herewith a Petition for an extension of time to respond to this Office Action.

**SUMMARY**

In view of the foregoing, it is respectfully submitted that the application is now in condition for allowance, and early action in accordance thereof is requested.

In the event there is any reason why the application cannot be allowed in this current condition, it is respectfully requested that the Examiner contact the undersigned at the number listed below to resolve any problems by Interview or Examiner's Amendment.

Respectfully Submitted,



Eugene Berman  
Reg. No. 22,587

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Eugene Berman  
Law Office of Eugene Berman  
26 Cedarwood Court  
Rockville, MD 20852

301 461-4635  
301 251-4032 FAX  
eugene.berman@verizon.net